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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/258,600 | 02/26/1999 | Dana M. Fowlkes | 60637DIV (50370) | 4086 |
| 7590 03/08/2006 | | | EXAMINER | |
| Edwards & Angell, LLP Attn: Peter C. Lauro P.O. Box 55874 Boston, MA 02205 | | | JOIKE, MICHELE K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/258,600

Applicant(s)

FOWLKES ET AL.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-102 and 109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-66, 77-93 and 100 is/are rejected.
- 7) ☒ Claim(s) 44-46, 48-62, 69-76, 96-97 and 102 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date April 27, 2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2005 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 63, 64, 65 and 100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 18, 19 and 1

of U.S. Patent No. 5,789,184. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), *In re Longi*, 759 F.2d 887, 224 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 100 is generic to all that is recited in claim 1 of U.S. Patent No. 5,789,184. That is, claim 1 of U.S. Patent No 5,789,184 falls entirely within the scope of claim 100, or in other words, claim 100 is anticipated by claim 1 of U.S. Patent No. 5,789,184. Specifically, a yeast cell having a pheromone system comprising a surrogate of claim 100 in the instant application includes the surrogate being a kinase of claim 1 of U.S. Patent No. 5,789,184. Claim 100 also includes an agonist/antagonist for the surrogate receptor. Although claim 1 does not specifically recite the terms "agonist" and "antagonist" it would be obvious to use an agonist or antagonist in those claims based upon the definition of a "modulator" set forth in U.S. Patent No. 5,789,184. Claims 63-65 are dependent on claim 100 in the instant application and have the exact same language as claims 17-19 in U.S. Patent No. 5,789,184, except for some redundant language added to the end of claim 63 in the instant application. Also, again, claims 63-65 depend from claim 100 in the instant application, and claims 17-19 depend from claim 1 in U.S. Patent No. 5,789,184. Therefore, claims 17-19 of U.S. Patent No 5,789,184 fall entirely within the scope of

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claims 63-65, or in other words, claims 63-65 are anticipated by claims 17-19 of U.S.

Patent No. 5,789,184.

Claims 66 and 77-93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20 and 29-45 of U.S. Patent No. 5,789,184.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

1. Claims 77-84 are directed to recombinant yeast cells, claims 29-36 of U.S. Patent No. 5,789,184, claims are also directed to recombinant yeast cells. Specifically, claim 29 of U.S. Patent No. 5,789,184 comprises recombinant yeast cells which comprise a pheromone system with an expressible gene construct encoding a kinase and an expressible gene construct encoding a signal sequence for secretion into the periplasmic space and modulation of the pheromone system provides the detectable signal. Claim 77 also comprises recombinant yeast cells which comprise a pheromone system with an expressible gene construct encoding a surrogate and an expressible gene construct encoding a signal sequence for secretion into the periplasmic space and modulation of the pheromone system provides the detectable signal. Claim 77 which depends on claim 100 also includes an agonist/antagonist for the surrogate receptor. Although claim 29 does not specifically recite the terms "agonist" and "antagonist" it would be obvious to use an agonist or antagonist in those claims based upon the definition of a "modulator" set forth in U.S. Patent No. 5,789,184.

2. The rest of the dependent claims, 78-84, of the instant specification set forth in the rejection above all comprise limitations that are present in corresponding claims U.S. Patent No. 5,789,184. Thus, these claims are also obvious because they all depend from a claim that is obvious in view of a claim in U.S. Patent No. 5,789,184. The corresponding claims are set forth below:

- (a) Claim 30 of U.S. Patent No. 5,789,184 makes instant claim 78 obvious because it recites that the yeast pheromone system is inactivated.
- (b) Claim 31 of U.S. Patent No. 5,789,184 makes instant claim 79 obvious because it further indicates that the cell further comprises a marker gene construct contains a marker gene in operative linkage with one or more transcriptional regulatory element.
- (c) Claim 32 of U.S. Patent No. 5,789,184 makes instant claim 80 obvious because the marker gene encodes a gene product that gives rise to a detectable signal.
- (d) Claim 33 of U.S. Patent No. 5,789,184 makes obvious instant claim 81 because the marker gene is HIS3.
- (e) Claim 34 of U.S. Patent No. 5,789,184 makes obvious instant claim 82 because the population of heterologous peptides includes at least 10^3 different peptide sequences.
- (f) Claim 35 of U.S. Patent No. 5,789,184 makes obvious instant claim 83 because the population of heterologous peptides includes at least 10^7 different peptide sequences.
- (g) Claim 36 of U.S. Patent No. 5,789,184 makes obvious instant claim 84 wherein the yeast cell is a *Saccharomyces* cell.

As such, claims 77-84 are obvious in light of these claims in U.S. Patent No. 5,789,184.

3. Claims 85-93 are directed to a method of identifying potential effectors of a yeast pheromone surrogate, claims 37-45 of U.S. Patent No. 5,789,184 also are directed to a method of identifying potential effectors of a yeast pheromone surrogate. Specifically, the method of claim 37 of U.S. Patent No. 5,789,184 comprises recombinant yeast cells which comprise a pheromone system with an expressible gene construct encoding a kinase and an expressible gene construct encoding a heterologous peptide, and modulation of the pheromone system provides the detectable signal. It also comprises isolating cells which exhibit the detection signal. The method of claim 85 also comprises recombinant yeast cells which comprise a pheromone system with an expressible gene construct encoding a surrogate and an expressible gene construct encoding a heterologous peptide, and modulation of the pheromone system provides the detectable signal. It also comprises isolating cells which exhibit the detection signal.

4. The remaining dependent claims of the instant specification set forth in the rejection above (concerning the methods) all comprise limitations that are present in corresponding claims of U.S. Patent No. 5,789,184. Thus, these claims are also obvious because they all depend from a claim that is obvious in view of a claim in U.S. Patent No. 5,789,184. The corresponding claims are set forth below:

(a) Claim 38 of U.S. Patent No. 5,789,184 makes obvious claim 86 of the instant application wherein the yeast pheromone receptor is inactivated.

(b) Claim 39 of U.S. Patent No. 5,789,184 makes obvious claim 87 of the instant application wherein the heterologous peptide includes a signal sequence for secretion into the periplasmic space.

(c) Claim 40 of U.S. Patent No. 5,789,184 makes obvious claim 88 of the instant application because it further indicates that the cell further comprises a marker gene construct contains a marker gene in operative linkage with one or more transcriptional regulatory element.

(d) Claim 41 of U.S. Patent No. 5,789,184 makes instant claim 89 obvious because the marker gene encodes a gene product that gives rise to a detectable signal.

(e) Claim 42 of U.S. Patent No. 5,789,184 makes obvious instant claim 90 because the marker gene is HIS3.

(f) Claim 43 of U.S. Patent No. 5,789,184 makes obvious instant claim 91 because the population of heterologous peptides includes at least 10^3 different peptide sequences.

(g) Claim 44 of U.S. Patent No. 5,789,184 makes obvious instant claim 92 because the population of heterologous peptides includes at least 10^7 different peptide sequences.

(h) Claim 45 of U.S. Patent No. 5,789,184 makes obvious instant claim 93 wherein the yeast cell is a *Saccharomyces* cell.

5. Claim 66 is directed to a method of assaying a peptide library, claim 20 of U.S.

Patent No. 5,789,184 also is directed to a method of assaying a peptide library.

Specifically, claim 20 of U.S. Patent No. 5,789,184, dependent on claims 16 and 1,

comprises a yeast culture comprising a plurality of yeast cells with the limitations of

claim 1 as described above, which express a surrogate and peptide of the library

determining whether the pheromone signal pathway is activated or inhibited by the

peptides. Claim 66, dependent on claims 62 and 100, also comprises a yeast culture

comprising a plurality of yeast cells with the limitations of claim 100 as described above,

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which express a surrogate and peptide of the library determining whether the pheromone signal pathway is activated or inhibited by the peptides. Claim 66 which depends on claim 100 also includes an agonist/antagonist for the surrogate receptor. Although claims 20, 16 or 1 do not specifically recite the terms "agonist" and "antagonist" it would be obvious to use an agonist or antagonist in those claims based upon the definition of a "modulator" set forth in U.S. Patent No. 5,789,184.

Allowable Subject Matter

Claims 47, 67, 68, 94, 95, 98, 99, 101 and 109 are allowed.

Claims 44-46, 48-62, 69-76, 96-97 and 102 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER